#### STATE OF MICHIGAN

# DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of
XXXXX
Petitioner

 $\mathbf{v}$ 

File No. 121669-001

Blue Cross Blue Shield of Michigan Respondent

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Issued and entered
this \_7th\_\_\_ day of December 2011
by R. Kevin Clinton
Commissioner

#### **ORDER**

#### I. PROCEDURAL BACKGROUND

On June 1, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The Commissioner reviewed the request and accepted it on June 8, 2011.

The Petitioner's benefits are defined in BCBSM's *Community Blue Group Benefit Certificate* (the certificate). The Commissioner notified BCBSM of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on June 17, 2011.

Because the case involves medical issues, the Commissioner assigned the case to an independent medical review organization. The reviewer's analysis and recommendations were submitted to the Commissioner on June 22, 2011. A copy of the complete report is being provided to the parties with this Order.

#### II. FACTUAL BACKGROUND

The Petitioner has Wolff-Parkinson-White syndrome, a disorder which affects the electrical signals in the heart. Her physician prescribed mobile cardiac outpatient telemetry (MCOT) services as a way to monitor her heart functions. The MCOT device was used from

November 15 to December 5, 2010. The charge was \$4,500.00. BCBSM denied coverage, concluding that the procedure is investigational and therefore not a benefit under the certificate.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference and issued a final adverse determination dated March 11, 2011, affirming its position.

### III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's heart monitoring as investigational?

#### IV. ANALYSIS

## BCBSM's Argument

BCBSM states that the Petitioner's health plan excludes coverage for services considered to be experimental or investigational. In its final adverse determination addressed to the Petitioner's authorized representative, BCBSM wrote:

... Our medical consultant reviewed the documentation provided, and determined that BCBSM considers procedure 93229 (wearable mobile cardiovascular telemetry w/ technical support) investigational. Long term studies concerning the effect on management and the outcome of management decisions for this technology is yet to be established. Thus, benefits are not warranted.

In this case, the patient is covered by the *Community Blue Group Benefits Certificate*. Page 6.3 explains that we do not pay for investigational services. Page 7.8 explains that investigational treatment has not been scientifically proven to be as safe and effective for the treatment of the patient's conditions as conventional treatment. Because the services were determined to be investigational, the patient is responsible for this charge.

## Petitioner's Argument

The Petitioner's representative, in the request for external review wrote:

... Contrary to the finding in the Plan Denial Letter, and the denial of the first appeal the Services are well-established as clinically effective and are a covered Plan benefit that were medically necessary and appropriate for this Patient. This conclusion is supported by the clinical determinations of the Ordering Physician, the standards of care in the medical community, studies in peer-reviewed and other medical literature, the terms of the Patient's Plan coverage and applicable law.

... This technology was approved by the FDA in November 1998 and is covered by the Level 1CPT codes 93229 for the technical component and 93228 for the professional component. Mobile cardiovascular telemetry services for the indication involved in this case have now been used effectively by the medical community in the United States for over a decade, and the health plans that cover this clinically valuable service for this indication include, among others, Medicare (which has covered this service since May 2001, and nationally prices the technical and professional components), Tricare, Highmark BC/BS, Independence BC/BS, Wellmark BCBS, Aetna, Cigna, and Humana.

## Commissioner's Review

The question of whether the Petitioner's heart monitor was investigational for treatment of her condition was presented to an independent medical review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician board certified in cardiology who has been in practice for more than 15 years. The reviewer is familiar with the medical management of individuals with the Petitioner's condition. The IRO reviewer's report includes the following analysis and conclusion:

[T]his case involves a 39 year-old female who has a history of Wolff-Parkinson-White syndrome status post ablation in 2009. At issue in this appeal is whether the wearable mobile cardiovascular telemetry with technical support services that the member received were investigational for diagnosis and treatment of her condition.

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[I]n the circumstances present in this case, if monitoring for dysrhythmias was thought to be medically necessary, then non-real time (off-line) monitoring devices, such as Holter monitoring or event monitoring, should have been sufficient for identification of both symptomatic and asymptomatic dysrhythmias. . . . [C]ontinuous off-line 24 to 48 hour Holter monitoring is able to effectively identify symptomatic or asymptomatic dysrhythmias that occur frequently. . . . [S]elf-activated, non-real time and non-continuous monitoring devices (event recorders) are effective at recording symptomatic dysrhythmias with less frequent symptoms. . . . [I]n cases of infrequent asymptomatic dysrhythmias that require identification, non-real time (off-line) monitoring devices with auto-triggering capability are sufficient. . . . [T]here was no documentation to indicate that the member would not have been able to effectively manage these standard types of monitoring devices. . . . [T]here was no evidence that these types of monitoring devices had been previously utilized to evaluate the member's condition. . . . [C]urrent consensus expert guidelines consider Holter monitoring and patient

activated event records appropriate initial tests for the evaluation of supraventricular dysrhythmias. . . . [C]ontinuous real-time monitoring by telemetry services was not medically necessary in this case because off-line analysis of a patient activated device, auto-triggered device or continuous Holter monitor would have been sufficient to identify dysrhythmias without jeopardizing patient safety. [Citations omitted]

. . . [T]he wearable mobile cardiovascular telemetry services with technical support services that the member received were investigational for diagnosis and treatment of her condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner finds that the mobile cardiac outpatient monitor is investigational for treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

#### V. ORDER

Respondent Blue Cross Blue Shield of Michigan's final adverse determination of March 11, 2011, is upheld. BCBSM is not required to provide coverage for the Petitioner's mobile cardiac outpatient telemetry device.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton Commissioner